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May 18, 1999

MERCK
Research Laboratories

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

RE: Docket No. 98N-1110
Draft Guidance on Agency Information Collection Activities: Submission for OMB Review; Comment Request; cGMP Regulations For Finished Pharmaceuticals

Merck & Co., Inc, is a leading worldwide, human health product company. Through a combination of the best science and state-of-the-art medicine, Merck's R & D pipeline has produced many of the most important pharmaceutical products on the market, today.

The medicines which Merck presents to worldwide health authorities for marketing approval are those that have met the highest technical standards available and those that are able to withstand the most critical regulatory review. Merck supports regulatory oversight of product development that is based on sound scientific principles and good medical judgment. It is in the interests of both sponsors and regulators to see that important therapeutic advances reach patients without unnecessary or unusual delays.

We have reviewed this Proposed guideline on Agency Information Collection Activities Related to cGMP Regulations for Finished Pharmaceuticals. We agree with the previous comments from a pharmaceutical trade association that the paperwork estimates provided by the Agency are too low. Our own experience suggests that 35 hours are required for the creation and review of an initial SOP and a minimum of 4 hours a year required for maintenance. We urge the Agency to reconsider its initial estimates of paperwork estimates for cGMP compliance.

Sincerely,

Dennis M. Erb

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Senior Director
Regulatory Affairs

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Food and Drug Administration

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